ORAL ARGUMENT NOT YET SCHEDULED

Lead Case No. 24-1151
Consolidated with Case Nos. 24-1185, 24-1182, 24-1202, 24-1237

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

UNITED STEEL, PAPER AND FORESTRY, RUBBER, MANUFACTURING, ENERGY, ALLIED INDUSTRIAL AND SERVICE WORKERS INTERNATIONAL UNION, AFL-CIO

Petitioners,

v.

ENVIRONMENTAL PROTECTION AGENCY,

Respondent,

Petition for Review of Final Rule

by the U.S. Environmental Protection Agency

PROOF BRIEF OF INTERVENOR-RESPONDENTS ALASKA COMMUNITY ACTION ON TOXICS AND SIERRA CLUB

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to D.C. Circuit Rules 27(a)(4) and 28(a)(1)(A), I certify that:

A. The parties, intervenors, and *amici* in these consolidated cases are:

Petitioners: United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFL-CIO in No. 24-1151; International Association of Machinists and Aerospace Workers, AFL-CIO in No 24-1182; Texas Chemistry Council and American Chemistry Council in No. 24-1185; Worksafe, Inc. in No. 24-1202; and American Fuel & Petrochemical Manufacturers and American Petroleum Institute in No. 24-1237.

Respondents: U.S. Environmental Protection Agency; Jane Nishida in her official capacity of Acting Administrator of the U.S. Environmental Protection Agency.[1]

Intervenor-Petitioner: Olin Corporation.

Intervenor-Respondents: Alaska Community Action on Toxics and Sierra Club.

[1] Jane Nishida is automatically substituted for Michael S. Regan pursuant to Federal Rule of Appellate Procedure 43(c)(2).

Amici: Chamber of Commerce of the United States of America and the National Association of Manufacturers.

B. Under review is the U.S. Environmental Protection Agency's final rule titled *Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA)*, 89 Fed. Reg. 37028 (May 3, 2024).

C. There are no related cases within the meaning of D.C. Circuit Rule 28(a)(1)(C).

DATED: January 17, 2025

/s/Tosh Sagar
TOSH SAGAR

RULE 26.1 DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 and D.C. Circuit Rule 26.1, Intervenor-Respondents Alaska Community Action on Toxics and Sierra Club state that they are non-governmental, non-profit advocacy organizations dedicated to the protection of public health and the environment. They have no parent corporations and no publicly held corporation owns a 10% or greater ownership interest in either of the entities.

DATED: January 17, 2025

/s/ Tosh Sagar
TOSH SAGAR

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GLOSSARY

Chamber	*Amici* Chamber of Commerce of the United States of America and National Association of Manufacturers
EPA	United States Environmental Protection Agency
HBCD	Cyclic Aliphatic Bromide Cluster
Industry	Industry-Petitioners American Chemistry Council, Texas Chemistry Council, American Fuel & Petrochemical Manufacturers, American Petroleum Institute; Intervenor-Petitioner Olin Corporation
Rule	Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA), 89 Fed. Reg. 37,028 (May 3, 2024).
Olin	Intervenor-Petitioner Olin Corporation
TCC	Petitioners American Chemistry Council, Texas Chemistry Council, American Fuel & Petrochemical Manufacturers, American Petroleum Institute
TSCA	Toxic Substances Control Act

INTRODUCTION

When Congress amended the Toxic Substances Control Act ("TSCA") in 2016, it created a new mandate to protect "potentially exposed or susceptible subpopulations." These are groups who face greater risk than the general population, either because they are more susceptible to a chemical's harmful effects or are exposed to more of a chemical.

EPA issued a rule that faithfully implements TSCA's mandates for conducting risk evaluations, thereby ensuring EPA can protect such subpopulations. First, the rule commits EPA to review "the conditions of use" for each chemical, meaning all conditions of use. This ensures that EPA will evaluate uses that might seem insignificant to healthy adults but can be highly risky to children, people with pre-existing conditions, and other susceptible groups who can be harmed at much lower doses.

Second, the rule commits EPA to making a risk determination for each chemical, rather than individual uses. In the real world, fenceline communities or indigenous people can be exposed to a chemical from a variety of activities, and those combined exposures can be highly risky. EPA's rule ensures it is able to consider those combined exposures and accurately characterize risk.

In challenging these two provisions, Industry asks this Court to rewrite TSCA, advancing interpretations that are divorced from TSCA's text and

structure.[2] For example, Industry argues that EPA must evaluate only those conditions of use with "the greatest potential for risk," while ignoring other conditions of use. But that phrase does not appear anywhere in TSCA. Similarly, Industry's argument that EPA must evaluate each condition of use, in isolation, is irreconcilable with TSCA's command to protect against "any combination" of uses that present unreasonable risk.

Industry's re-write would vitiate TSCA's protections for at-risk subpopulations. Indeed, EPA conducted risk evaluations just as Industry now asks—excluding conditions of use and making risk determinations use-by-use—and the result was predictable: EPA overlooked activities that posed unreasonable risk, including risks to fenceline communities and other at-risk subpopulations.

Tellingly, Industry's briefs have little-to-nothing to say about how their interpretations comport with TSCA's mandates for subpopulations. Indeed, Olin seeks to further weaken EPA's ability to protect subpopulations, challenging the rule's provision that addresses unique risks to "overburdened communities."

[2] "Industry" refers to TCC (petitioners in Case Nos. 24-1185 and 24-1237) and Olin, who adopts TCC's arguments, Olin Br. at 8.

Ultimately, Industry's arguments are premised on its misreading of the statute and rule. The Court should reject industry's invitation to rewrite TSCA and thereby undo the protections Congress enacted less than a decade ago.

STATUTES AND REGULATIONS

All applicable statutes and regulations cited are included in the Brief for TCC.

STATEMENT OF THE CASE[3]

I. TOXIC CHEMICALS ARE UBIQUITOUS, AND MANY GROUPS FACE UNIQUE RISKS.

The modern world is awash in toxic, commercial chemicals that have not been reviewed for safety. *See* EPA Br. at 31. From so-called forever chemicals to microplastics, toxic chemicals are everywhere—the air we breathe, the water we drink, the products in our homes—and are linked with a number of adverse health

[3] Intervenor-Respondents adopt EPA's statement of issues 1, 2, and 5, and corresponding sections of its standard of review. EPA Br. at 5-6, 17-18.

outcomes, including: cancer, decreased fertility, and autism.[4] Yet, the effects of toxic chemicals are not felt or experienced evenly.

1. Children are especially susceptible to toxic chemicals. Early childhood is marked by phases in which major organs, like the brain, are developing and therefore acutely sensitive. Exposures to seemingly small amounts of toxic chemicals during these "windows of vulnerability" are associated with damage to vital organ systems. TENDR Consensus at A118; *see* NEJM at 2, JA____. The cancer risk from early life exposures to carcinogens "can be about 10-fold higher than the risk from an exposure of similar duration occurring later in life." EPA, Guidelines for Carcinogen Risk Assessment at 1-17 (2005) ("EPA Carcinogen Guidelines"), JA____.

Exposures to toxic chemicals occur even before birth. Studies demonstrate that 90% of pregnant women have detectable levels of toxic chemicals in their bodies, and many of these chemicals can cross the placenta and get to the

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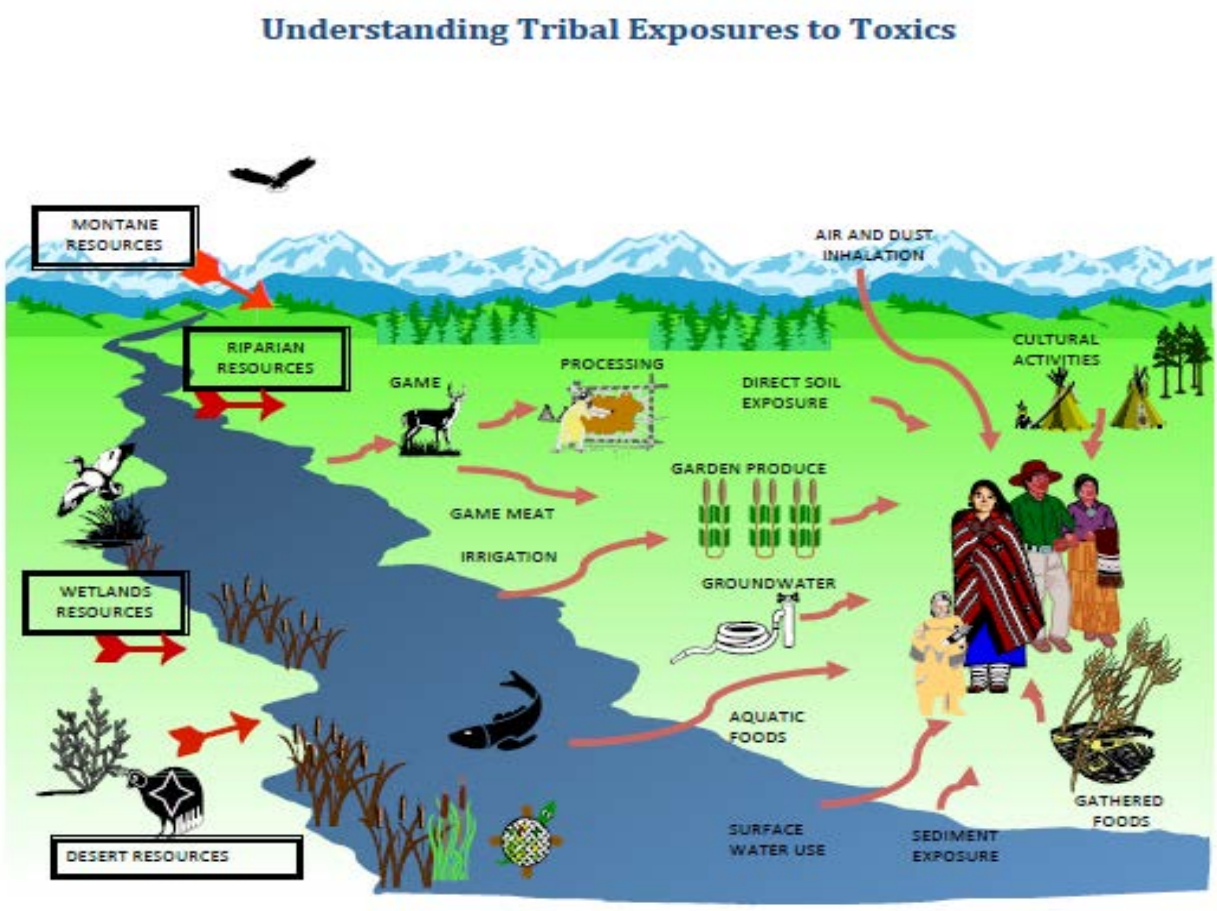
[4] Deborah Bennett, *Targeting Environmental Neuro-Developmental Risks. The TENDR Consensus Statemen*t, 124 Env't Health Persps. A118, A118 (2016) ("TENDR Consensus"), https://pmc.ncbi.nlm.nih.gov/articles/PMC4937840/pdf/EHP358.pdf, JA____; Consortium for Childs.' Env't Health et al., *Manufactured Chemicals and Children's Health — The Need for New Law*, New Eng. J. of Med. (2025) ("NEJM"), https://doi.org/10.1056/nejmms2409092, JA____; Univ. of Cal. S.F., Microplastics in the Air May Be Leading to Lung and Colon Cancer (2024), https://www.ucsf.edu/news/2024/12/429161/microplastics-air-may-be-leading-lung-and-colon-cancers (last accessed Jan. 17, 2025).

developing fetus. TENDR Consensus at A118; NEJM at 2 (summarizing harms from prenatal and in utero exposure), JA____.

2. In communities throughout the country—Geismar, Baytown, Rubbertown, Freeport, and Beaumont, to name just a few—facilities sited next to schools, parks, churches, and homes spew toxic pollutants into the air and water. Earthjustice Comments Part 2 at 7-10 (2023) ("Comments"), JA____-JA____; *see* Declarations at DEC-009-17, DEC-027-28, Doc. #2061336. Some neighborhoods are surrounded by multiple facilities that collectively release tens of thousands of pounds of a single chemical. Comments at 8-9, JA____-JA____. Consequently, people living in fenceline communities face disproportionately high exposures and risks from toxic chemicals. *See* 89 Fed. Reg. 37,028, 37,039-40 (May 3, 2024).

3. Indigenous communities' traditional foods are being contaminated by the release of toxic chemicals into the environment. Fishing, hunting, and gathering wild foods are not only central cultural practices for many indigenous communities in the United States but are often necessary for basic subsistence. *See* Nat'l Tribal Toxics Council, Understanding Tribal Exposures to Toxics at 3, 7 (2015) ("NTTC"), https://nttc.sfo3.cdn.digitaloceanspaces.com/Docs/NTTC-Understanding_Tribal_Exposures_to_Toxics-2015-06-19.pdf. The release of persistent pollutants can contaminate these foods and expose communities through

unique pathways, as illustrated by EPA's tribal partnership group on toxic chemicals:



NTTC at 8.

This contamination results in indigenous people facing anywhere from "10 to 100 times" more exposure than the general population. *Id.* at 10; *see also* Declarations at DEC-038-39; EPA, Response to Public Comments at 8 (2024) ("Response to Comments"), JA____; 89 Fed. Reg. at 37,040. These problems are particularly pronounced in indigenous communities in Alaska, who have some of

the highest levels of certain pollutants in their bodies of any people on earth. Declarations at DEC-040.

II. TSCA MANDATES EPA PROTECT AT-RISK SUBPOPULATIONS FROM UNREASONABLY RISKY CHEMICALS.

EPA's brief summarizes how Congress responded to decades of EPA inaction by significantly amending TSCA in 2016 to create a new and effective process for regulating chemicals in commerce. EPA Br. at 6-8. The amended TSCA creates a three-step process for (1) prioritizing, (2) evaluating, and (3) regulating existing chemicals. *Id.* at 8-9 (summarizing 15 U.S.C. § 2605).

TSCA's core provision governing risk evaluations requires EPA to "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment…including an unreasonable risk to a potentially exposed or susceptible subpopulation…under the conditions of use." 15 U.S.C. § 2605(b)(4)(A). If EPA determines "the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance…or that any combination of such activities, presents an unreasonable risk," then EPA must regulate "to the extent necessary so that the chemical substance…no longer presents such risk." 15 U.S.C. § 2605(a). Together, these provisions mandate that, if EPA determines the chemical presents unreasonable risk under the conditions of use, EPA must proceed to regulate the chemical to eliminate the unreasonable risk.

There are four especially relevant features of the statutory scheme.

1. EPA must protect "potentially exposed or susceptible subpopulation[s]." 15 U.S.C § 2605(b)(4)(A); *see id.* § 2605(a). These are groups of individuals who "may be at greater risk than the general population of adverse health effects" either because they are: (1) more "susceptib[le]" to the chemical; or (2) exposed to more of the chemical. *Id.* § 2602(12).[5]

In each risk evaluation, EPA must "identif[y]" those subpopulations that are "relevant" to the chemical being evaluated and determine whether the chemical poses an unreasonable risk to those subpopulations. *Id.*§ 2605(b)(4)(A). If the chemical does, EPA must regulate to eliminate "such risk." *Id.* § 2605(a); S. Rep. 114-67 at 7 (2015) ("EPA must…establish risk management measures necessary and sufficient to protect those populations.").

2. Because TSCA ties the scope of risk management regulations to the results of the risk evaluation, accurately characterizing risk—particularly the risk faced by subpopulations—is necessary to fulfill TSCA's health-protective mandates. 15 U.S.C. § 2605(a). And accurately characterizing risk requires

[5] "[P]otentially exposed or susceptible subpopulations" are also referred to as "at-risk" or "relevant" subpopulations herein.

accurately assessing exposure, because under TSCA, risk is a function of "exposure" and "hazard."[6] 15 U.S.C. § 2605(b)(4)(F).

Thus, if EPA underestimates exposure, it will underestimate risk, which can "prevent EPA from putting necessary protections in place." 89 Fed. Reg. at 37,032. First, if EPA erroneously concludes that a chemical substance does not present unreasonable risk, EPA is not permitted to regulate. *See* 15 U.S.C. § 2605(a). Second, even if EPA determines there is unreasonable risk, underestimating that risk may still lead to under-protective regulations because EPA has underestimated what is needed to eliminate "such risk." *Id*.

3. TSCA requires EPA to protect against the risks posed by a chemical throughout the entirety of its lifecycle, from its initial "manufacture" to ultimate "disposal." *Id.* And, to do so, it requires EPA to evaluate the risks posed by the "chemical substance" "under the conditions of use," *id.* § 2605(b)(4)(A), which it likewise defines as the circumstances encompassing the entire lifecycle, from "manufacture[]" to "dispos[al]," *id.* § 2602(4).

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[6] Simplistically, risk is a function of: (1) the harms caused by the chemical and the dose of the chemical that causes the harm (hazard); and (2) the amount of the chemical people face under the conditions of use (exposure).
See EPA, Guidance to Assist Interested Persons in Developing and Submitting Draft Risk Evaluations Under the Toxic Substances Control Act at 16-21 (2018) ("TSCA Risk Evaluation Guidance"), JA____-JA____; 40 C.F.R. § 702.39(c)-(e); EPA Br. at 11-12.

This lifecycle regulatory system is particularly important for protecting at-risk subpopulations, as conditions of use that pose seemingly low risk to the general population may still be harmful to susceptible groups. If EPA ignores such conditions of use when conducting the risk evaluation, EPA cannot assess the associated exposure and will overlook the associated risk. Declarations at DEC-022.

4. TSCA requires EPA to evaluate and protect against the risks posed by the chemical substance, holistically, not just individual activities considered in isolation. EPA must protect against unreasonable risk from "the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or…any combination of such activities." 15 U.S.C. § 2605(a) (emphasis added).

Thus, even where an activity is seemingly not particularly risky when viewed in isolation, this provision expressly recognizes that the chemical might present unreasonable risk if EPA evaluates the activity in combination with others. *Id.* Accordingly, TSCA mandates that risk determinations be made on the "chemical substance…under the conditions of use" and authorizes EPA to "aggregate" exposures that result from different conditions of use. *Id.*§ 2605(b)(4)(A) (emphasis added), (F)(ii).

TSCA's focus on the chemical, rather than individual activities, is important to protecting at-risk subpopulations. In the real world, some groups face disproportionately high exposure from multiple conditions of use, like fenceline communities exposed to a chemical from "different conditions of use occurring at multiple nearby facilities." 89 Fed. Reg. at 37,038. If EPA evaluates conditions of use in isolation, EPA will underestimate the combined exposures such people face. *Id.* at 37,032; Declarations at DEC-023-25.

III. HISTORY OF THE RISK EVALUATION RULE

In January 2017, EPA proposed a rule governing risk evaluations that required EPA to: (1) assess all conditions of use of a chemical; and (2) determine whether the chemical substance poses an unreasonable risk. 82 Fed. Reg. 7,562, 7,578, 7,580 (Jan. 19, 2017).

After a change in administration, EPA finalized a substantially rewritten rule, in which it asserted the authority to: (1) exclude conditions of use from the scope of the risk evaluation; and (2) make use-by-use risk determinations. *See, e.g.*, 82 Fed. Reg. 33,726, 33,729, 33,730, 33,744, 33,751 (July 20, 2017). Over the next four years, EPA completed multiple risk evaluations under this rule. *See* EPA, Ongoing and Completed Chemical Risk Evaluations under TSCA ("Risk Evaluation Chart"), https://www.epa.gov/assessing-and-managing-chemicals-

under-tsca/ongoing-and-completed-chemical-risk-evaluations-under (last updated Jan. 15, 2025).

Following another administration change, EPA reversed course, committing to evaluate relevant activities that EPA had previously excluded and announcing it would issue single risk determinations for each chemical, rather than use-by-use determinations. EPA, EPA Announces Path Forward for TSCA Chemical Risk Evaluations (2021) ("Path Forward"), JA____. EPA applied these policies to new and ongoing risk evaluations and to revise already completed evaluations.

EPA then adopted the final, revised rule challenged here, which: (1) requires EPA to evaluate all conditions of use; (2) commits EPA to making a single risk determination for each chemical; and (3) identifies overburdened communities as an example of a potentially exposed or susceptible subpopulation. 89 Fed. Reg. at 37,052, 37,053, 37,054 ("Rule").

SUMMARY OF ARGUMENT

I. Industry challenges the Rule's provision stating that EPA "will not exclude conditions of use from the scope of the risk evaluation," 40 C.F.R. § 702.37(a)(4). TCC Br. at 16-26. That challenge fails because the regulation implements the best reading of the statute.

A. TSCA's core directive—that EPA evaluate risks from a "chemical substance…under the conditions of use"—is best read to require EPA to evaluate

all conditions of use of the chemical. 15 U.S.C. § 2605(b)(4)(A). Ordinarily, when "the" precedes a plural noun—like conditions of use—it means "all." *Ass'n of Am. R.Rs. v. Costle*, 562 F.2d 1310, 1315 (D.C. Cir. 1977). Accordingly, once EPA has determined the set of circumstances that constitute "the conditions of use," EPA must evaluate all of them. 15 U.S.C. § 2605(b)(4)(A). Structure and purpose—particularly the obligation to evaluate risks to subpopulations—confirm the plain meaning is the best reading.

B. As Industry reads TSCA, Congress ordered EPA to "review only those conditions of use that pose the greatest potential for risk," but those words appear nowhere in TSCA. TCC Br. at 16. The Court cannot insert Industry's preferred words into the statute. *United States v. Neely*, 2024 WL 5229878, at *2-*3 (D.C. Cir. Dec. 27, 2024).

TSCA's structure also forecloses Industry's pick-and-choose approach, because it would upend the step-by-step statutory process. *Johnson v. Guzman Chavez*, 594 U.S. 523, 543 (2021). EPA would be allowed to exclude conditions of use at the outset of a risk evaluation—before EPA had assessed either: (1) the dose at which the chemical causes harm, including to susceptible groups like children; or (2) the levels of exposure faced in the real world. Doing so would vitiate TSCA's mandate to protect subpopulations, negating key provisions and TSCA's core purpose. *King v. Burwell*, 576 U.S. 473, 492-93 (2015)

C. EPA conducted risk evaluations using Industry's pick-and-choose approach and, as a result, overlooked significant risks to relevant subpopulations.

D. Industry's arguments about surplusage, timeframes, and legislative history are meritless.

II. Industry challenges the Rule's provision that "EPA will make a single determination" for each chemical substance, 40 C.F.R. § 702.39(f)(1). TCC Br. at 26-35; Olin Br. at 9-17. That challenge fails because the regulation implements the best reading of the statute.

A. The best reading of TSCA is that EPA must make one determination as to whether "a chemical substance" poses an unreasonable risk. 15 U.S.C. § 2605(b)(4)(A). This reading aligns with TSCA's plain language describing the aim of a risk evaluation and gives meaning to surrounding statutory provisions.

B. Industry interprets TSCA to mandate risk evaluations and determinations for each individual condition of use. This use-by-use approach is incompatible with TSCA's directive for EPA to address unreasonable risk posed by a "combination" of chemical activities, 15 U.S.C. §2605(a), and its authorization to consider "aggregate" exposures to a chemical, *id.* § 2605(b)(4)(F)(ii). *See Becerra v. Empire Health Found., for Valley Hosp. Med. Ctr.*, 597 U.S. 424, 442-45 (2022). Industry never grapples with these provisions.

And Industry's interpretation that every condition of use requires its own risk evaluation would lead to an absurd result: an exponentially increasing number of risk evaluations. *See Milavetz, Gallop & Milavetz, P.A. v. United States*, 559 U.S. 229, 252 (2010).

C. Industry's arguments rest on a flawed reading of the Rule and mischaracterize how risk evaluations and determinations function under the single-determination approach. The Rule requires EPA to characterize and evaluate the risks associated with the actual conditions of use, and prior risk evaluations conducted using a single-determination approach show EPA does just that.

D. Industry raises a litany of concerns regarding overbroad risk management rules that it asserts will result from the single-determination approach. These concerns ignore EPA's obligations under TSCA and are premature.

III. Olin's challenge to EPA's identification of "overburdened communities" as an example of a subpopulation that may be potentially relevant in future risk evaluations fails. EPA's action is supported by record evidence that Olin does not dispute. Olin Br. at 22-23 (challenging 40 C.F.R. § 702.33).

ARGUMENT

I. THE RULE CODIFIES TSCA'S MANDATE TO EVALUATE ALL CONDITIONS OF USE.

Industry challenges the Rule's commitment to evaluate all conditions of use, which implements TSCA's directive to evaluate the chemical "under the conditions of use," 15 U.S.C. § 2605(b)(4)(A). TCC Br. at 16-26 (challenging 40 C.F.R. § 702.37(a)(4)).

Industry contends that if Congress meant for EPA to review all conditions of use, it would have used the word "all." TCC Br. at 18; *see* Chamber Br. at 8-9. But the argument that Congress could have "use[d] the word 'all' rather than the word 'the'…is perhaps the weakest of all statutory construction arguments, particularly where, as here…[the] alternative language…has substantially the same meaning as the language which Congress did employ." *Costle*, 562 F.2d at 1316 (cleaned up).

Ordinary meaning, structure, and purpose confirm that the direction to evaluate a chemical under "the" conditions of use is best read to require EPA to evaluate "all" conditions of use. EPA Br. at 22-29. Thus, once EPA has determined what circumstances constitute "the conditions of use" for a chemical, EPA must evaluate all of them. The Rule is lawful because it implements that single, best

reading of the statute. EPA Br. at 22-40;[7] *see Loper Bright Enters. v. Raimondo*, 603 U.S. 369 (2024).

A. EPA's Reading is the Best Reading.

1. TSCA's plain text mandates that risk evaluations include all of a chemical's conditions of use by directing EPA to conduct risk evaluations "to determine whether a chemical substance presents an unreasonable risk…under the conditions of use." 15 U.S.C. § 2605(b)(4)(A) (emphasis added); EPA Br. at 24.

When "the" precedes a plural noun, like conditions of use, it ordinarily means "all." *E.g.*, *Costle*, 562 F.2d at 1315 (concluding that the statutory term "the equipment and facilities" "subsume[s] all such equipment and facilities"); *Kaufman v. Allstate New Jersey Ins. Co.*, 561 F.3d 144, 155 (3d Cir. 2009) ("the definite article preceding the term 'claims' indicates that 'the claims asserted' means all the claims asserted"); *Frazier v. Pioneer Ams. LLC*, 455 F.3d 542, 546 (5th Cir. 2006) (similar).

By contrast, where Congress intended EPA to address only a subset of conditions of use, it said so expressly. *E.g.*, 15 U.S.C. § 2605(c)(2)(C) (describing what EPA must consider in deciding whether to ban or restrict "a specific condition

[7] Intervenor-Respondents adopt EPA's arguments in support of 40 C.F.R. § 702.37(a)(4).

of use"); *id.* § 2605(g)(1) (allowing exemptions for "a specific condition of use" that meets certain criteria); EPA Br. at 25 (citing § 2604(h)(1)(A), referring to "the specific conditions of use"). The Court "must give effect to, not nullify, Congress' choice to include limiting language in some provisions but not others." *Gallardo v. Marstiller*, 596 U.S. 420, 431 (2022).

2. TSCA's structure and purpose require comprehensive risk evaluations that assess the real-world exposures resulting from all of a chemical's uses. EPA Br. at 27-29. Comprehensive evaluations are needed to fulfill the requirement that EPA evaluate risks to "potentially exposed or susceptible subpopulation[s]." 15 U.S.C. § 2605(b)(4)(A).

For example, individual conditions of use that result in relatively low exposures (and thus seemingly low risks) might pose significant risks to groups with "greater susceptibility…due to [] lifestage or a pre-existing condition." 89 Fed. Reg. at 37,040. A child might face an order of magnitude more risk from the same condition of use as a healthy adult. *E.g.*, EPA Carcinogen Guidelines at 1-17, JA____. EPA would overlook that risk if it fails to include the condition of use in the risk evaluation.

Additionally, "[t]here may be situations where certain individual conditions of use are associated with relatively lower exposures, but when considered in

aggregate contribute to unreasonable risk." 89 Fed. Reg. at 37,032. For example, in a fenceline community near multiple facilities, some of which manufacture the chemical and others that process the chemical into products, people may be exposed from both conditions of use. *See id*. at 37,038, JA____; Earthjustice Comments Part 1 at 8, n.41 (2023), JA____. Even if each condition of use does not seem particularly risky when viewed in isolation, an evaluation may show that the chemical poses an unreasonable risk if the community members' exposures are aggregated and assessed in combination. *See* 15 U.S.C. § 2605(a), (b)(4)(F)(ii).[8]

Failure to evaluate all conditions of use will lead to an incomplete picture of risk and "prevent EPA from putting necessary protections in place to mitigate such risk to the general population or potentially exposed or susceptible subpopulations." 89 Fed. Reg. at 37,032. Thus, evaluating all conditions of use conforms to TSCA's structure and advances its core purposes.

3. Because text and structure confirm that construing the to mean all is the best reading of the statute, Industry's argument that Congress needed to be even

[8] Industry's argument that this provision requires EPA to "focus risk evaluations on sentinel exposures" by excluding uses, TCC Br. at 21, ignores that this very provision also authorizes EPA to "aggregate…exposures," 15 U.S.C.§ 2605(b)(4)(F)(ii), including exposures resulting from "different combinations of conditions of use," Response to Comments at 36, JA____; *see* 89 Fed. Reg. at 37,032.

clearer by using "all" fails. *Costle*, 562 F.2d at 1316 ("This is perhaps the weakest of all statutory construction arguments…."); *see Torres v. Lynch*, 578 U.S. 452, 472-73 (2016) (Congress need not write statute "in more crystalline fashion."). The Rule is lawful because it implements the best reading of TSCA.

B. Industry's Pick-And-Choose Reading is Atextual and Upends TSCA's Step-by-Step Structure.

1. Industry's reading has no basis in TSCA's text and requires the Court to insert words into the statute.

EPA explains how Industry advances an impermissible, atextual interpretation. EPA Br. at 29-40.

1. Industry's interpretation is that "Congress intended EPA to review only those conditions of use that pose the greatest potential for risk," TCC Br. at 16 (emphasis added); *see id.* at 11, 17-19; *see* Chamber Br. at 8 (similar). But this formulation is not in § 2605: TSCA mandates that EPA determine whether a chemical presents an unreasonable risk "under the conditions of use," without using the term "potential for risk" or anything like it. 15 U.S.C. § 2605(b)(4)(A) (absence); *see id.* § 2605 (absence).

"Because the Court does not read into statutes words that aren't there," Industry's interpretation must be rejected. *Neely*, 2024 WL 5229878, at *2 (cleaned up).[9]

2. Industry argues that the phrase "as determined by the Administrator" in the definition of "conditions of use" "provides a clear and unambiguous directive" for EPA to determine which conditions of use should be evaluated and which should be excluded "based on their different potential for exposure and contribution to risk." TCC Br. at 18-19 (citing 15 U.S.C. § 2602(4)).

But this provision does not mention potential "risk" or "exposure" at all. *See id*. § 2602(4) (absence). Once again, Industry asks this Court to impermissibly insert language into TSCA that Congress did not enact. The Court need not go any further to reject Industry's interpretation "because [EPA's] interpretation does not require reading any additional words into the statute, whereas [Industry's] would." *Neely*, 2024 WL 5229878, at *2 (cleaned up).

[9] Industry argues EPA must evaluate the conditions of use with "the greatest potential for risk" or those "with the greatest exposure potential." *Compare* TCC Br. at 6, 16, *with id.* at 3, 10 (emphases added). But risk and exposure are different under TSCA, *see* EPA Br. at 29, and uses with low exposures might be highly risky. Industry's inability to decide on which is the best reading is further confirmation that its arguments are atextual and meritless.

As EPA's brief makes clear, the phrase "as determined by the Administrator" is best read as requiring EPA to make a judgment—applied to the evidence about the particular chemical—about what circumstances meet the statutory definition. EPA Br. at 30-31; *see also*, 89 Fed. Reg. at 37,032. Industry and the Chamber agree that this provision requires EPA to exercise judgment as to whether a particular circumstance "qualifies" as a condition of use; but they assert that the phrase confers a second level of discretion—to determine whether that condition of use "warrants consideration" or can be excluded. Chamber Br. at 8; *see* TCC Br. at 18-19 (similar).

This doubly discretionary reading fails. Once EPA has exercised its judgment to determine what the conditions of use are, the provision does not then confer "a roving license to ignore the statutory text" and exclude a condition of use. *Massachusetts v. EPA*, 549 U.S. 497, 533 (2007).

Indeed, the Ninth Circuit has already rejected Industry's argument that the phrase "as determined by the Administrator" confers such discretion. *Safer Chems., Healthy Fams. v. EPA*, 943 F.3d 397, 422-25 (9th Cir. 2019) (holding unlawful a prior regulation that categorically excluded circumstances that that met the statutory definition of conditions of use). That court heard the same arguments made here that "TSCA should be interpreted to allow the Agency to focus on quickly regulating the worst risks." *Id.* at 423. The court disagreed, holding "the

statute grants EPA discretion to determine the conditions of use for each chemical substance...[but] that discretion may only be exercised within the bounds of the statutory definition itself." *Id.* at 425.

So too here: to adopt Industry's interpretation "would be to contravene the statute's clear language and structure and nullify textually applicable provisions meant to limit EPA's discretion." *NRDC v. Regan*, 67 F.4th 397, 402 (D.C. Cir. 2023) (cleaned up).

2. Industry's reading upends TSCA's step-by-step structure, thereby vitiating the mandate to protect at-risk subpopulations.

EPA cogently explains how Industry's interpretation would thwart TSCA's comprehensive system for evaluation and regulation. EPA Br. at 31-38.

Additionally, Industry's interpretation inverts TSCA's step-by-step structure and undermines the procedures that ensure EPA can protect at-risk subpopulations. Industry's interpretation must be rejected because courts "cannot interpret federal statutes to negate their own stated purposes." *King*, 576 U.S. at 493 (citation omitted) (rejecting interpretation as contrary to structure).

1. Industry's interpretation turns TSCA on its head by allowing EPA to exclude a condition of use, based on its supposed "potential for risk," before EPA has taken the mandated steps needed to characterize the risk of any condition of

use. TCC Br. at 16; *see Johnson*, 594 U.S. at 543 (rejecting interpretation inconsistent with the "sequential steps of the [statutory] process"); EPA Br. at 36 (Industry "puts the cart before the horse").

Risk evaluation under TSCA is a step-by-step process of (1) scoping, (2) hazard and exposure assessment, (3) risk characterization, and finally (4) risk determination. EPA Br. at 10-13 (summarizing statutory provisions); *see* TSCA Risk Evaluation Guidance at 13, JA____. Characterizing risks is one of the final steps, requiring EPA to "integrate and assess available information on hazards and exposures for the conditions of use…including…information on potentially exposed or susceptible subpopulations." 15 U.S.C. § 2605(b)(4)(F)(i); *see* TSCA Risk Evaluation Guidance at 20 ("risk characterization integrates information for the preceding components of the risk assessment," i.e. hazard and exposure assessment), JA____.

Industry's interpretation is an end-run around this step-by-step process for characterizing risk. It is during the hazard assessment that EPA seeks to determine the level at which a chemical causes harm—whether 0.01 grams per day or 0.0000001 grams per day. *See* 40 C.F.R. § 702.39(c)(5) (requiring dose-response assessment); TSCA Risk Evaluation Guidance at 18-19 (describing required dose-response assessment), JA____-JA____. At the exposure assessment, EPA seeks to assess how much of the chemical people face under the conditions of use—

whether 0.005 grams per day or 50 grams per day. *See* 40 C.F.R. § 702.39(d); TSCA Risk Evaluation Guidance at 16-18 (describing exposure assessment), JA____-JA____. Then by integrating these assessments (and accounting for other relevant factors), EPA evaluates whether exposures are above or below a level that presents a risk of injury. 40 C.F.R. § 702.39(e); TSCA Risk Evaluation Guidance at 20-21, JA____-JA____.[10]

If EPA excludes a condition of use before it has even attempted these steps, it will not have characterized the risk associated with that condition of use. Thus, any conclusion about the relative potential for risk of the excluded condition of use would be baseless. Industry's interpretation must be rejected as an end-run around TSCA's step-by-step process.

2. Moreover, allowing this end-run around TSCA's step-by-step process would vitiate the mandate to evaluate risks to relevant subpopulations. 15 U.S.C. § 2605(b)(4)(F)(i) (requiring EPA to "integrate and assess available information on

[10] In some cases, EPA may qualitatively assess the exposure and risk associated with a condition of use. *See* EPA Br. at 18-19; 40 C.F.R. § 702.39(e)(1)(i). EPA typically does so where it has already assessed hazard and determined the dose at which the chemical causes harm. Thus, even where EPA does a qualitative assessment, it is still taking the required statutory steps, not excluding the condition of use from the analysis entirely (as Industry's interpretation would allow). *See* EPA Br. at 38.

hazards and exposures for the conditions of use…including…information on potentially exposed or susceptible subpopulations" (emphasis added)).

Uses of a chemical that generate relatively low exposures can still be highly risky to susceptible people. If EPA has not even attempted to establish how toxic the chemical is to potentially susceptible groups, it cannot rationally conclude that a condition of use poses trivial risk.

That analysis of susceptibility occurs at the hazard assessment step, where EPA considers whether harm to relevant susceptible groups—like children, pregnant people, or people with preexisting diseases—may occur at very low levels. 40 C.F.R. § 702.39(c)(4). There, using the scientific literature, EPA: (1) identifies factors that might make a group more susceptible, like "windows of developmental susceptibility"; and (2) seeks to ascertain the level (i.e., the dose) of a chemical that is harmful, including to susceptible groups. TSCA Risk Evaluation Guidance at 19-20 (describing dose-response assessment for relevant subpopulations), JA____-JA____; *see* EPA Carcinogen Guidelines at 1-4, 1-18 (describing importance of assessing dose-response for children), JA____, JA____. And if there are data gaps or other uncertainties in the evaluation, EPA may apply numerical adjustments, known as "uncertainty factors," to estimate whether a dose is harmful to relevant subpopulations. TSCA Risk Evaluation Guidance at 20,

JA____. Together these steps allow EPA to draw rational conclusions about the potential dose that harms children and other susceptible groups.

Without an understanding of the dose of the chemical that causes harm, EPA has no basis to say whether seemingly low exposures are risky. By skipping over the required analysis, Industry's reading would allow EPA to exclude uses that do present an unreasonable risk to relevant subpopulations. This would vitiate the mandate to protect susceptible subpopulations.

Industry cannot reconcile its reading with TSCA's mandate to protect subpopulations, nor does it try. *See* TCC Br. at 16-26 (absence). That silence speaks volumes. Industry's attempted end-run around these core requirements must be rejected. *King*, 576 U.S. at 493.

C. Risk Evaluations Conducted Using Industry's Pick-And-Choose Approach Overlooked Significant Risks, Including Risks to Relevant Subpopulations.

In prior risk evaluations, EPA used the pick-and-choose-approach to exclude conditions of use and missed significant risks as a result, including risks to relevant subpopulations. These prior evaluations further confirm that the pick-and-choose approach would negate TSCA's central mandates to evaluate the risk to relevant subpopulations and to protect against such risk. *King*, 576 U.S. at 493.

For example, for the chemical 1,4-dioxane, EPA excluded multiple conditions of use from its original risk evaluation; then, upon further analysis, EPA found those excluded conditions of use contribute to 1,4-dioxane's unreasonable risk, including to fenceline communities. *See* EPA, 1,4-Dioxane Unreasonable Risk Determination at 4, 5, 7-8 (2024) ("1,4-Dioxane 2024 Determination"), JA____. At the outset of the risk evaluation process in 2017, EPA "exclude[d] from the scope of [its] risk evaluation conditions of use associated with 1,4-dioxane generated as a byproduct in manufacturing, industrial and commercial uses." EPA, 1,4-Dioxane Risk Evaluation at 38 (2020) (emphasis added), JA____; *see* EPA, 1,4-Dioxane Scope of the Risk Evaluation at 8 (2017), JA____. Therefore, EPA did not evaluate or characterize the full range of exposures and risks associated with the excluded conditions of use. 1,4-Dioxane 2024 Determination at 5, JA____.

EPA later conducted a supplemental analysis that assessed the previously excluded byproduct-conditions-of-use and found significant cancer risks to fenceline communities and workers. 1,4-Dioxane 2024 Determination at 12, 16, JA____, JA____-JA____. In its revised risk determination, EPA found that these excluded conditions of use contributed to the unreasonable risk to human health posed by 1,4-dioxane. *See id.* at 3-4, 24-27, JA____-JA____, JA____-JA____.

D. Industry's Remaining Arguments Are Meritless.

1. Industry relies on scattered TSCA provisions that cannot support its interpretation.

Industry's arguments misread a number of TSCA's provisions, and, in any event, these provisions could not override the clear directive to evaluate all conditions of use. *See Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001) ("Congress … does not … hide elephants in mouseholes.").

1. Industry argues the Rule renders several provisions of TSCA superfluous, but each of these provisions has an obvious purpose under EPA's interpretation.

First, Industry contends that the scoping provision, which directs EPA to identify the "conditions of use" that it "expects to consider," would be superfluous if EPA lacks discretion to determine which conditions of use to evaluate. TCC Br. at 20-21 (citing 15 U.S.C. § 2605(b)(4)(D)). But this provision has utility under EPA's reading, allowing EPA to update the conditions of use if EPA receives information later in the process that either: (1) identifies new conditions of use; or (2) confirms uses have been discontinued. EPA Br. at 33-34; *see* Response to Comments at 17, JA____; *e.g.*, EPA, HBCD Risk Evaluation at 54-55 (2020)

("HBCD 2020 Evaluation") (adding a condition of use after the scoping phase because EPA "learned of an ongoing use"), JA____.[11]

Second, Industry argues that EPA's interpretation renders TSCA's preemption provisions "inoperative and superfluous." TCC Br. at 11; *see also, id.* at 21-22 (citing 15 U.S.C. § 2617(c)). Limiting the scope of preemption to those "conditions of use…included in the scope of the risk evaluation" is not superfluous under EPA's interpretation, because chemicals can be used in new ways over time. *Contra id.* at 21 (cleaned up). Thus, if a company later begins to process a chemical into a new product that was not included in the scope, state regulation would not be preempted.

Finally, the Chamber argues that EPA's interpretation "ignor[es]" and "fails to give effect" to the section of TSCA that deals with coordinating risk management activities across different statutes and agencies. Chamber Br. at 11 (cleaned up); *see id.* at 10-11 (citing 15 U.S.C. § 2608). This section requires EPA to make a predicate "determin[ation]" regarding a chemical's "risk" before relying

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[11] Indeed, the Ninth Circuit has already rejected a substantially similar argument. *Safer Chems.*, 943 F.3d at 419. There, the court concluded that the phrase "plans to consider"—which the court read as synonymous with "expects to consider"—"simply refers to the Agency's role in determining what the conditions of use are for a particular substance," and "unambiguously do[es] not grant EPA the discretion" to exclude conditions of use. *Id.*

on another EPA statute to manage that risk or referring risk management to another agency. *See* 15 U.S.C. § 2608(a)(1), (b)(1). Consistent with these provisions, EPA could: (1) conduct a risk evaluation that characterizes the risks associated with all conditions of use; (2) make a determination that chemical presents unreasonable risk; and then (3) for any particular condition of use, "determine[], in the Administrator's discretion" whether risks should be managed under TSCA or another statute. *See id.* Thus, these provisions are not superfluous under EPA's reading, but simply address how EPA will manage risks, the step after risk evaluation.

2. Industry contends EPA's interpretation is inconsistent with the timeframe for risk evaluations because EPA has missed its TSCA deadlines since implementing an "all conditions of use" approach to risk evaluations. TCC Br. at 22 (citing 15 U.S.C. § 2605(b)(4)(G)). *Post hoc ergo propter hoc*: EPA also missed its deadlines when using Industry's preferred pick-and-choose approach. *See* Risk Evaluation Chart.

2. Industry's invocation of a lone Senator's statement cannot muddy TSCA's clear mandate.

Industry argues that its interpretation of TSCA aligns with Congress' intent, as shown by the floor statement of a single senator. *See* TCC Br. at 23-24. But "[f]loor statements from…Senators cannot amend the clear and unambiguous

language of a statute." *Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 457 (2002); *see Pub. Citizen, Inc. v. Rubber Mfrs. Ass'n*, 533 F.3d 810, 819 (D.C. Cir. 2008) (ordinarily, no "controlling weight" is given to such statements).

Regardless, Industry's understanding of this cherry-picked statement is contradicted by statements of other Senators. *See* 162 Cong. Rec. at S3516 (June 7, 2016) ("The definition of 'conditions of use'…plainly covers all uses of a chemical substance…."); *see NLRB v. SW Gen., Inc.*, 580 U.S. 288, 307 (2017) (rejecting statutory interpretation supported by Senator's floor statement, noting that the "very next speaker…offered a contradictory account").

II. THE RULE CODIFIES TSCA'S MANDATE TO MAKE A SINGLE DETERMINATION AS TO WHETHER A CHEMICAL SUBSTANCE PRESENTS UNREASONABLE RISK

Industry challenges the Rule's provisions requiring a single risk determination for each chemical substance. TCC Br. at 26-35 (challenging 40 C.F.R. § 702.39(f)(1)); Olin Br. at 8-17 (same).

The tools of statutory construction confirm that EPA must issue a single risk determination for each chemical substance undergoing a risk evaluation. EPA Br. at 42-46. Industry's proposed alternative interpretation, the use-by-use approach, is

atextual and not a permissible reading. EPA Br. at 46-56. As the Rule codifies the best reading of TSCA, Industry's challenge fails. EPA Br. at 42-58.[12]

A. EPA's Reading Is the Best Reading.

1. TSCA's operative provision governing risk evaluations mandates that EPA "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment." 15 U.S.C. § 2605(b)(4)(A) (emphasis added). This expresses Congress' clear intent that EPA evaluate the risk posed by "a chemical substance" and make a single risk determination for the chemical, not its individual conditions of use. EPA Br. at 42-43.

2. TSCA's structure confirms that Congress intended EPA to conduct a single risk evaluation that results in a single risk determination for each chemical substance. EPA identifies numerous provisions that support that reading. EPA Br. at 43-45, 48-49. Additionally, the definition of "potentially exposed or susceptible subpopulation" reinforces that risks arise "from exposure to a chemical substance" not individual conditions of use. 15 U.S.C. § 2602(12) (emphasis added).

[12] Intervenor-Respondents adopt EPA's arguments in support of 40 C.F.R. § 702.39(f)(1), except for the argument regarding the scope of preemption following a risk management rule, EPA Br. at 52, which is unnecessary to identify the best reading.

Further supporting the single-determination approach are: (1) TSCA's mandate to protect against unreasonable risks from "any combination of … activities" that constitute the conditions of use, 15 U.S.C. § 2605(a); and (2) the authorization to "aggregate … exposures to a chemical substance under the conditions of use," *id.* § 2605(b)(4)(F)(ii). In the real world, people face "combined exposures across multiple conditions of use." 89 Fed. Reg. at 37,035. Accordingly, even if individual conditions of use seem low risk when viewed in isolation, the chemical can still present an unreasonable risk when a person faces aggregated exposures from multiple conditions of use.

For example, multiple commercial and consumer products containing a chemical may contaminate a community's drinking water such that the combined contamination contributes to the chemical's unreasonable risk. *See* 1,4-Dioxane 2024 Determination at 16, 26-29, JA____, JA____-JA____. Or an individual condition of use that carries risks below EPA's benchmark for unreasonable risk can combine with similar uses to exceed the benchmark. *See* EPA, Asbestos Part 2 Risk Evaluation at 192-93, 422-26 (2024), JA____.

The provisions requiring EPA to protect against risky "combinations" of activities and to "aggregate" exposures, further confirm that EPA's task is to determine whether the chemical substance, rather than individual conditions of use, presents unreasonable risk. 15 U.S.C. § 2605(a), (b)(4)(F)(ii); *see* Response to

Comments at 23 (explaining the single-determination approach "enables the Agency's risk determinations to better reflect the potential for combined exposures across multiple [conditions of use]"), JA____.

B. Industry's Use-by-Use Reading is Atextual and Would Lead to Absurd Results.

Industry's interpretation is that EPA must conduct risk evaluations and make risk determinations for each condition of use. TCC Br. at 28-29, 31 ("[T]he only harmonious reading requires individual Risk Determinations based on the distinct conditions of use identified in the scope."); Olin Br. at 13 ("Each evaluation, for its given condition of use, would lead to its own 'determination.'"). EPA explains why Industry's reading is not a permissible interpretation of TSCA. *See* EPA Br. at 46-56. Three further points demonstrate why Industry's reading must be rejected.

1. Under Industry's reading, EPA does not "evaluate the total risks of a chemical, but each risk, based upon the individual ways the chemical is used." TCC Br. at 28. That use-by-use approach is irreconcilable with the mandate to protect against risks from "combination[s]" of condition of use and the authorization to "aggregate" exposures. 15 U.S.C. § 2605(a), (b)(4)(F)(ii).

Tellingly, Industry does not attempt to square its reading with these provisions. TCC Br. (absence); *see also* Olin Br. (similar absence); Chamber Br. (similar absence). Because Industry's approach would prevent EPA from assessing

the real-world exposures and risks people face—those arising from combinations of multiple activities—it must be rejected. *Becerra*, 597 U.S. at 442-45 (rejecting interpretation that "fits poorly" with statutory structure).

2. Industry's reading, that each condition of use must get its own evaluation, would lead to an absurd result: exponential growth in the number of chemicals EPA is required to evaluate. *See* Olin Br. at 13 ("Each evaluation, for its given condition of use, would lead to its own 'determination.'"); TCC Br. at 29, 31 (similar).

TSCA's establishes a one-in, one-out structure: "upon the completion of each risk evaluation," EPA "shall designate at least one high-priority substance," which EPA must then evaluate.[13] 15 U.S.C. § 2605(b)(3)(C), (b)(3)(A) (emphases added). Accordingly, under the use-by-use approach, the conclusion of a risk evaluation for each individual condition of use would require EPA to identify a new chemical substance and then conduct risk evaluations for each of that chemical's conditions of use.

Currently, EPA is evaluating 20-plus chemicals that collectively have hundreds of conditions of use. *See* Risk Evaluation Chart. Industry's interpretation

[13] This one-in, one-out requirement does not apply to manufacturer requested evaluations. 15 U.S.C. § 2605(b)(3)(C).

would require EPA, after completing risk evaluations for each of those hundreds of conditions of use, to identify an equal number of chemicals and begin risk evaluations on each of the conditions of use associated with those hundreds of chemicals. EPA would have to complete each evaluation in three-and-a-half years. 15 U.S.C. § 2605(b)(4)(G). This pattern of exponential growth would continue without end. Such an absurd result must be rejected. *Milavetz,* 559 U.S. at 252 (rejecting interpretation that "would produce an absurd result").

C. Industry's Arguments Misunderstand the Single-Determination Approach.

Industry argues that the single-determination approach violates TSCA because it "completely reads out the concept of 'conditions of use.'" TCC Br. at 29; *see also id.* at 29-30 (asserting it "removes evaluation of the potential exposures to the substance…under actual use cases"); Olin Br. at 10 (similar).

Industry is wrong. Under the single-determination approach, EPA's analysis is tied to the conditions of use as demonstrated by: (1) the Rule's plain text; and (2) recently completed risk evaluations where EPA used the single-determination approach.

1. The plain text of the Rule requires EPA to assess the conditions of use when making a single risk determination.

Industry argues the single-determination approach "disregards potential exposures to the substance under specific conditions of use." TCC Br. at 29. Not

so: the Rule expressly requires EPA to consider relevant "exposures under the conditions of use." 40 C.F.R. § 702.39(d)(1) .

Similarly, Industry argues EPA fails to give effect to TSCA's requirement to "'integrate and assess'" hazard and exposure information "'for the conditions of use.'" TCC Br. at 30 (quoting 15 U.S.C. § 2605(b)(4)(F)(i)). Once again, the Rule does what Industry demands, requiring EPA to "[i]ntegrate the hazard and exposure assessments" to estimate risks "under the conditions of use." 40 C.F.R. § 702.39(e)(1)(i).

Moreover, under the Rule, EPA does "tie" its risk determination to a chemical's conditions of use. *Contra* TCC BR. at 29. EPA "consider[s] the risks posed under the conditions of use and, where EPA makes a determination of unreasonable risk, EPA will identify the conditions of use that significantly contribute to such determination." 40 C.F.R. § 702.39(f)(3) (emphasis added). And in doing so, EPA will necessarily identify those conditions of use that do not significantly contribute to the determination.

2. Previous uses of the single-determination approach confirm EPA assesses the actual conditions of use.

EPA has completed several risk evaluations under the single-determination approach, and EPA: (1) assessed exposures and characterized risk for the conditions of use; and (2) identified both the conditions of use that contribute to

the unreasonable risk determination and those that do not. These evaluations further refute Industry's arguments that the single-determination approach evaluates risk in the abstract. *Contra* TCC Br. 29, 31; Olin Br. 10.

1. In 2021, EPA announced that it would implement the single-determination approach for ongoing risk evaluations. Path Forward, JA____. Just as in the Rule, EPA confirmed that under the single-determination approach, "EPA will continue to assess and analyze each condition of use." *Id.*

In subsequent risk evaluations, EPA assessed the exposures from the conditions of use and characterized the associated risks. *E.g.* EPA, Tris(2-chloroethyl) Phosphate Risk Evaluation at 162-251 (exposure), 320-55 (risk) (2024), JA____- JA____, JA____- JA____. As one example, in making a risk determination for Tris(2-chloroethyl) Phosphate, EPA identified the 10 conditions of use that contributed to the unreasonable risk posed by that chemical as well as the 11 that did not. *Id.* at 22, JA____.

2. EPA also revised some risk determinations that were initially completed under a use-by-use approach, replacing them with a single determination for the chemical. These revised determinations did "tie" the determination to the conditions of use. *Contra* TCC Br. at 29.

For example, in EPA's initial risk evaluation for HBCD, EPA made use-by-use risk determinations and found that six of HBCD's conditions of use presented unreasonable risk. *See* HBCD 2020 Evaluation at 43, JA____. When EPA adopted a single determination that HBCD presented unreasonable risk, its determination was "driven by risks associated" with the same six conditions of use, "considered singularly or in combination." EPA, HBCD Final Revised Unreasonable Risk Determination at 1 (2022), JA____.

Industry's arguments are based on a misunderstanding of the single-determination approach; they therefore fail.

D. Industry's Concerns about Overbroad Risk Management Rules are Meritless and Premature.

Industry argues that the single-determination approach could lead EPA to "regulate particular uses of a chemical that do not present an unreasonable risk," TCC Br. at 33; *see also id.* at 33-34; *see* Olin Br. at 9 (similar).

1. Again, Industry does not grapple with EPA's authority to regulate conditions of use that do not seem unreasonably risky in isolation but, in "combination," contribute to a chemical's unreasonable risk. *See* Point II.A, *supra*; 15 U.S.C. § 2605(a).

2. Moreover, "there may be scenarios where it is necessary to regulate conditions of use that do not directly pose unreasonable risk, such as when

elimination of a risk to downstream users/consumers necessitates upstream regulation of manufacture, processing or distribution in commerce." Response to Comments at 23, JA____.

For example, EPA found that certain products containing n-Methylpyrrolidone contribute to unreasonable risk when used in commercial settings, but not consumer ones. Yet, EPA proposed to regulate importing, processing, and distribution of consumer products so that they would not be improperly used in commercial settings. *See* 89 Fed. Reg. 51,134, 51,151-52 (June 14, 2024) (describing "Container Size Restrictions and Labeling Requirements").

TSCA allows these approaches, authorizing EPA to apply regulatory measures "to [the] substance…to the extent necessary so that the chemical substance…no longer presents such risk." 15 U.S.C. § 2605(a) (emphases added). In selecting among measures that can eliminate unreasonable risk from the chemical substance, TSCA requires EPA to consider a variety of factors, including costs, benefits, and economic consequences. *See id.* § 2605(c)(2)(A)-(C). Thus, if EPA ultimately seeks to regulate a condition of use that it has determined does not contribute to unreasonable risk, EPA will have to rationally explain that decision in light of those factors, and that decision will be judicially reviewable. EPA Br. at 56, 58.

3. Accordingly, Industry's hypothetical concerns about overbroad risk management rules are properly addressed in challenges to actual risk management rules. And for similar reasons, its due process arguments fail. *See* EPA Br. at 56-58.

III. THE RULE LAWFULLY IDENTIFIES OVERBURDENED COMMUNITIES AS AN EXAMPLE OF A SUBPOPULATION THAT MAY BE RELEVANT IN FUTURE RISK EVALUATIONS.

Olin argues that EPA authorized itself to identify "overburdened communities" as potentially relevant subpopulations in future risk evaluations even though they "do not meet [TSCA's] standard." Olin Br at 22, 23 (challenging 40 C.F.R. § 702.33).[14] Intervenor Respondents adopt EPA's arguments demonstrating that Olin's arguments fail on the merits. EPA Br. at 87-88.

1. EPA's regulation is consistent with the statute and supported by the record. EPA's identification of "overburdened communities" is reflective of an unfortunate but objective reality: "there are communities of people that may experience disproportionate risks from chemicals due to greater exposure or susceptibility to environmental and health harms." 89 Fed. Reg. at 37,031. EPA recognized fenceline communities and indigenous communities who rely on

[14] Olin does not challenge EPA's authority to identify, by rule, additional examples beyond those in § 2602(12). *See* Olin Br. at 22-23 (absence).

subsistence fishing as examples of such communities. 89 Fed. Reg. at 37,039-40; Response to Comments at 7-8, JA____- JA____.

These conclusions are supported by the record. *E.g.*, EPA, Cumulative Impacts Research (2022), JA____-JA____; Comments at 6-10, JA____-JA____. And Olin does not dispute them. *See* Olin Br. at 22-23 (absence). Accordingly, the regulation is consistent with TSCA and lawful.

2. Rather than address EPA's rationale, Olin cherry-picks two phrases from the Rule's preamble to claim that EPA will identify overburdened communities—irrespective of greater exposure or susceptibility—based on either (1) "environmental harms in general" or (2) a "lack of opportunity for public participation." Olin Br. at 22 (cleaned up).

This is a strawman. In each risk evaluation, "EPA will look to whether 'overburdened communities' are subject to exposure or susceptibility greater than the general population." 89 Fed. Reg. at 37,039.

Indeed, the two phrases plucked by Olin reflect EPA's accurate summary of decades of research found in the record: (1) existing environmental harms—such as significant sources of other pollutants—make communities more susceptible; and (2) communities are shut out of political processes that determine where pollution goes and, consequently, have pollution forced on them. 89 Fed. Reg. at

37,039 ("Such disproportionality can be as a result of …lack of opportunity for public participation…."); Comments at 4, 6-10, JA____, JA____-JA____. As the record demonstrates: "There is substantial empirical evidence that elucidates how pollution, climate, and other environmental stressors, socioeconomic disadvantage, lack of environmental assets, and health vulnerability tend to be clustered spatially in patterns which are described as recurrent, persistent, and systematic in nature." Cumulative Impacts Research at 6 (citing studies), JA____.

Again, Olin does not dispute those record-based findings. Olin Br. at 22-23 (absence). Regardless, EPA has committed to identifying overburdened communities case-by-case, 89 Fed. Reg. at 37,039, so the Court should reject Olin's attempts to muddy the waters by cherry picking preamble statements out of context. *Stand Up for Cal. v. U.S. Dep't of Interior*, 879 F.3d 1177, 1182 (D.C. Cir. 2018) (upholding decision where "the agency's path may reasonably be discerned").

CONCLUSION

The Court should deny Industry's petitions for review.

DATED: January 17, 2025

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMIT

Counsel hereby certifies, in accordance with Federal Rule of Appellate Procedure 32(g)(1), that the foregoing brief contains 8,755 words, excluding the parts exempted by Federal Rule of Appellate Procedure 32(f), as counted by counsel's word processing system, and thus complies with the 9,100-word limit established in the Court's September 9, 2024, order.

Further, this document complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5) and (a)(6) because this document has been prepared in a proportionally spaced typeface using Microsoft Word for Microsoft 365 using size 14 Times New Roman font. *See* Fed. R. App. P. 32(a)(5), (6).

DATED: January 17, 2025

/s/ Tosh Sagar
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CERTIFICATE OF SERVICE

I hereby certify that on, I served the foregoing brief, and all accompanying declarations, on all counsel of record through the Court's electronic filing system.

DATED: January 17, 2025

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